



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#15

JUN 27 1991

Food and Drug Administration
Rockville MD 20857

Re: Exosurf Neonatal
Docket No. 90E-0343

Charles E. Van Horn
• Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,312,860 filed by Burroughs Wellcome Company, under 35 U.S.C. 156. The patent claims the human drug product Exosurf Neonatal, NDA 20-044.

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In the December 20, 1990, issue of the Federal Register, the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before June 18, 1991, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. FDA, therefore, considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Lawrence A. Nielsen
Head, Patent Department
Burroughs Wellcome Company
3030 Cornwallis Road
Research Triangle Park, NC 27709